

<b>Office Action Summary</b>	<b>Application No.</b> 09/771,382	<b>Applicant(s)</b> PEAK ET AL.	
	<b>Examiner</b> VANESSA L. FORD	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33,34,49-52,54,55 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33-34,49-52,54-55 and 57-60 is/are allowed.
- 6) ☒ Claim(s) 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20090415</u> .                           |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                          |

## DETAILED ACTION

1. This Office action is responsive to Applicant's after-final response filed March 25, 2009. A Non-Final rejection is set forth below:

### ***New Ground of Rejection Necessitated by Applicant's Amendment***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 61 is rejected under 35 U.S.C. 103(a) as unpatentable over Peak et al (*WO 99/31132, published June 1999*).

Claim 61 is drawn to an isolated protein having at least 90% sequence identity to SEQ ID No:23 or SEQ ID No:35 wherein the isolated protein is not a wild-type NhhA polypeptide and wherein the isolated protein is immunogenic.

Peak et al teach proteins from *Neisseria meningitidis* and immunogenic compositions as well as pharmaceutical compositions containing the polypeptide (see the Abstract and pages 29-30). Peak et al defines the term "fragment" to include deletion mutants and small peptides, for example of at least 6, preferably at least 10 and more preferably at least 20 amino acids in length, which comprise antigenic determinants or epitopes (page 11). Therefore, Peak et al teach NhhA polypeptides

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that are not the wild-type. Peak et al teach a *N. meningitidis* protein ORF40-1 protein (SEQ ID NO:5) that has the amino acid sequence that is 98.1% identity to SEQ ID NO:23 and a *N. meningitidis* protein ORF40-1 protein (SEQ ID NO:5) that has the amino acid sequence that is 99.3% identity to SEQ ID NO:35. Peak et al contemplate polypeptides that are fragments or variants or derivatives of the polypeptide set forth in SEQ ID No. 5 (page 3).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make polypeptides that include antigenic determinants or epitopes of NhhA polypeptides of the invention because Peak et al contemplate fragments or variants or derivatives of NhhA polypeptides and defines the term "fragment" to include deletion mutants and small peptides, for example of at least 6, preferably at least 10 and more preferably at least 20 amino acids in length, which comprise antigenic determinants or epitopes (page 11). Thus, Peak et al teach NhhA polypeptides having at least 90% sequence identity to SEQ ID No:23 or SEQ ID No:35 wherein the isolated protein is not a wild-type NhhA polypeptide and wherein the isolated protein is immunogenic.

#### ***Status of Claims***

4. Claims 33-34, 49-52, 54-55 and 57-60 are allowed.

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/  
Examiner, Art Unit 1645  
April 10, 2009